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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/888,063 | 06/22/2001 | Corey E. Nislow | CYTOP003 | 6972 |
| 22852 | 7590 | 10/19/2005 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | MILLER, MARINA I | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/888,063 | NISLOW ET AL. | |
| | Examiner | Art Unit | |
| | Marina Miller | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,9-12,14,15,23-27,29,30,32,33,37-41,43,44,47-53,55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,9-12,14,15,23-27,29,30,32,33,37-41,43,44,47-53,55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Handwritten mark

DETAILED ACTION

Applicants' submission filed on 9/02/2005 is acknowledged. Claims 2-5, 9-12, 14-15, 23-27, 29-30, 32-33, 37-41, 43-44, 47-53, and 55-56 are pending. Claims 1, 6-8, 13, 16-22, 28, 31, 34-36, 42, 45-46, and 54 are cancelled. Claims 2-5, 9-12, 14-15, 23-27, 29-30, 32-33, 37-41, 43-44, 47-53, and 55-56 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Information Disclosure Statement

Information Disclosure Statement (IDS) filed 3/7/2005 has been considered in part. The examiner appreciates applicant's apprising her of copending sister application listed on the IDS. The examiner considered and initialed US applications which were not considered in the previous office action. The references which were considered in the previous office action have been crossed out to avoid duplication upon printing. The examiner maintains that office actions from US applications that have not yet matured into an issued patent are not qualified under "other information" recited in 37 C.F.R. 198(a)(1) because these office actions are "communications" and have not been published or otherwise made publicly available. Applicant is reminded that examination, *i.e.*, office actions, in US applications is generally considered confidential until such time as a patent is issued. Therefore, the office actions of not publicly available applications have not been considered and are crossed out on the IDS. Applicants is hereby assured, however, that the contents of all applications listed on the IDS have been considered by the examiner.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on p. 7. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

First Paragraph

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 4, 5, 19, 20, 34, 35, 45, and 46 were rejected for lack of enablement in the Office Action mailed 12/9/2004. Applicants cancelled claims 19, 20, 34, 35, 45, and 46. Claims 4 and 5 were further rejected the Office Action mailed 6/6/2005 as being non-enabled because they recite deleting every one of the non-essential genes in a parental strain, which is unpredictable as being directed to a complex and undefined result for a complex organism.

Applicants argued in their answer filed 9/02/2005, that claim 4 is enabled based on the disclosure coupled with information known in the art (p. 16-17 of the applicants' answer). Applicants asserted that the genome of *S.cerevisiae* has been sequenced in the entirety and analyzed/modified systemically to yield a complete set of congenic deletion mutations, and

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therefore establishing which gene is non-essential would merely require the routine screening of the mutants for viability. *Id.* This argument was considered, but is found not persuasive. One cannot make or use the instant invention because neither the instant claims nor the specification disclose the definition of “non-essential” gene. Genes may be essential or not for survival in poor or rich media, in budding stage, during replication, *etc.*, and therefore scientists would define the term “non-essential gene” differently depending on the purpose of their research. Also, although the genome of *S.cerevisiae* has been sequenced, not all genes are presently identified and classified, and therefore, one cannot identify “each” non-essential gene, such that a collection of strains with a deletion mutant for “each non-essential gene” is enabled.

For the reasons stated above, the rejection is maintained.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 9-12, 14-15, 23-27, 29-30, 32-33, 37-41, 43-44, 47-53, and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 23, 47, 48, and 55, as amended, recite the limitation “wherein the genetically modified cell strains are separately grown and imaged” in the step of making cell features. It is not clear whether “growing and imaging” recited in the step of making is intended to be an active, positive method step. It is also not clear whether “imaging” in the step of making is different from the step of imaging the genetically modified cell strains. As the intended

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limitation is not clear, claims 2-5, 9-12, 14-15, 23-27, 29-30, 32-33, 37-41, 43-44, 47-53, and 55-56 are indefinite.

Claim Rejections - 35 USC § 103

Claims 2-4, 9-12, 14-15, 23-27, 29-30, 32-41, 43-44, 47-53, and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashby, U.S. Patent 6,518,035, in view of Giuliano, U.S. Patent 6,416,959 and Price, U.S. Patent 5,548,661.

Applicants amended the claims by adding the limitation “wherein the genetically modified cell strains are separately grown and imaged.” Applicants argue that Ashby does not disclose separate growing and imaging the modified cell strains, and therefore the instant claims are not obvious over the prior art of record. In the response, the examiner points to Giuliano, U.S. Patent 6,416,959, col. 35, line 65-67; col. 37-38; col. 40; col. 42; col. 46, line 19-20; col. 67; figs. 19, 25, and 27-28, wherein Giuliano discloses separate growing and imaging of cells. Price also discloses separate growing and imaging different strains (col. 23, line 66 through col. 24, line 55). For the reasons stated above, rejection is maintained.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashby, U.S. Patent 6,518,035, in view of Giuliano, U.S. Patent 6,416 and Price, U.S. Patent 5,548,661, as applied to claims 2-4, 9-12, 14-15, 23-27, 29-30, 32-41, 43-44, 47-53, and 55-56 above, and further in view of Winzeler, *Science*, 285:901-906 (6 August 1999).

Applicants argue that Ashby does not disclose separate growing and imaging the modified cell strains, and therefore the instant claims are not obvious over the prior art of record.

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For the reasons stated in the rejection of claims 2-4, 9-12, 14-15, 23-27, 29-30, 32-41, 43-44, 47-53, and 55-56 under 35 U.S.C. 103(a) above, rejection is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D., can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARJORIE A. MORAN
PRIMARY EXAMINER

Marina Miller
Examiner
Art Unit 1631

MM

Marjorie A. Moran
10/13/05